DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

***Administrator***
Washington DC 20201

August 27, 2002

Dear Commissioner:

The purpose of this letter is to provide you with new information that may affect Medicare Supplemental insurance markets in your state. Attached is a detailed explanation of how innovative benefits in Medigap policies may have room for expansion. Included is a clarification of section 1882 (p) of the Social Security Act, as well as the position of the Centers for Medicare & Medicaid Services (CMS) regarding preferred provider networks offered by Medicare SELECT issuers.

Innovative benefits in one or more of the ten standardized Medigap plans are allowed at the discretion of the state. Expanding innovative benefits provides an opportunity to include through Medigap policies such benefits as case management or disease management services, prescription drug, vision, dental, and hearing benefits that cover examinations, etc.

I am hopeful you will find the attached information useful. Any questions should be directed to Gale Arden, Director of the Private Health Insurance Group within CMS at (410) 786-6810.

Sincerely,

///original signed///

Thomas A. Scully
Administrator

Attachment

**Attachment**

**Medicare Supplement Detailed Information**

## I. Purpose

The purpose of this attachment is to clarify the interpretation of section 1882 (p) of the Social Security Act, concerning the addition of "innovative benefits" to a Medicare supplemental insurance (Medigap) policy and to set forth CMS's position regarding preferred provider networks offered by Medicare SELECT issuers. In addition, this attachment explains how an innovative benefit is different from a "vendor discount."

In summary, we believe that there is room for expansion of innovative benefits in Medigap policies. The Social Security Act and accompanying regulations provide flexibility for states to approve "innovative benefits" in Medigap policies. Depending on how a Medigap or Medicare SELECT issuer structures their policies, these benefits could include such items and services as: prescription drug, vision, dental, and hearing benefits, case management or disease management services, and various kinds of wellness promotion programs.

## II. Medicare Supplement Policies and Innovative Benefits

### A. Background

The Social Security Act (the Act) establishes a comprehensive regulatory scheme governing the issuance of Medicare supplement policies (commonly referred to as Medigap). When Federal requirements for Medigap policies were first enacted in 1980, Congress incorporated by reference into section 1882 of the Act standards developed by the National Association of Insurance Commissioners (NAIC). Since that time, the NAIC Model Regulation for Medicare Supplement Policies has served as the guidepost of the Federal minimum standards for Medigap policies. The NAIC Model Regulation has been amended several times to take into account statutory changes that have been enacted to the Medicare program.

The Act permits states to approve Medigap policies, but only in accordance with a state regulatory framework that meets certain federal requirements and standards. The Act specifically provides that no benefit packages may be offered under a Medigap policy unless it meets the NAIC standards. Id. § 1395ss(p)(4)(A). However, with the approval of the state, the issuer of a Medigap policy "may offer new or innovative benefits *in addition to* the benefits provided in a policy that otherwise complies with" the applicable standards. Id. § 1395ss (p)(4)(B) (emphasis added). The NAIC Model Regulation permits states to approve policies that cover additional benefits by incorporating the new or innovative benefits provision of the Act. See Model Regulation § 8C(11). If a state's regulatory program fails to meet the minimum federal requirements, the Secretary of Health and Human Services ("Secretary" or "HHS") must certify that the policy meets the federal requirements. 42 U.S.C. § 1395ss(a).

The original 1979 NAIC Model Regulation contained only minimum benefit standards. Policies were allowed to, and commonly did, exceed the minimum benefits standards. The result was a market place in which Medicare beneficiaries had no way to evaluate the relative benefits of one policy over another or to compare different policies' premiums. Consequently, the Omnibus Budget Reconciliation Act of 1990 (OBRA'90) required all Medigap policies to be standardized. The NAIC, aided by an advisory committee of industry and consumer representatives and other interested parties, was given the opportunity to design no more than 10 standardized benefit packages. Generally, these policies would be the only ones that could be offered nationwide.[i] From the time states implemented the OBRA'90 standards (generally by July 1992), it has been illegal to offer or sell any policy that does not conform to one of the 10 standardized packages, designated Medigap plans A to J.[ii]

However, so as to promote innovation in the market place, section 1882(p)(4)(B) of the Act provides that Medigap policies can offer "innovative benefits" --

> With the approval of the State, the issuer of a [Medigap] policy may offer new or innovative benefits in addition to the benefits provided in a policy that otherwise complies with the applicable 1991 NAIC Model Regulation…. Any such new or innovative benefits may include benefits that are not otherwise available and are cost-effective and shall be offered in a manner which is consistent with the goal of simplification [i.e., standardization] of [Medigap] policies. (Emphasis added.)

Section 1882(p) (7) also clarifies that vendor discounts can be provided along with the standardized Medigap packages, but not part of such packages, by providing that –

> This subsection shall not be construed as preventing an issuer of a [Medigap] policy who otherwise meets the requirements of this section from providing, through an arrangement with a vendor, for discounts from that vendor to policyholders or certificateholders for the purchase of items or services not covered under its [Medigap] policies. (Emphasis added.)

A survey conducted by the NAIC in 1999 indicates that relatively few states have ever received issuer requests to add any kind of an innovative benefit. Even fewer states have approved any such requests; and no state has ever approved large numbers of issuer requests to add innovative benefits. It appears that states have preferred to adhere to the idea that benefit packages should be kept standard as much as possible so that consumers can compare benefits and issuers will be forced to compete on the basis of price and service alone. This survey confirmed anecdotal information CMS had gathered over the past decade that the states' authority to approve innovative benefits has not been abused. If anything, the authority has been arguably under-utilized.[iii]

### B. Innovative Benefits and Vendor Discounts

There is continuing confusion over the distinction between an "innovative benefit" and what constitutes a "vendor discount." The structure of section 1882(p), described above, makes it clear that the two concepts are different: Vendor discount programs are not innovative benefits. However, in practice, telling the two apart is not always easy.

#### *1. Innovative Benefits*

The first characteristic of an innovative benefit is that it is an added benefit that is proposed by an issuer. It must be an actual benefit (i.e., the issuer pays some portion of the cost of a covered item or service rather than just arranging for a reduced price for that item or service, all of which the policyholder pays out-of-pocket). The benefit must be attached to one of the standard Medigap policies. It cannot be a totally new or different policy. Nor can it be a benefit that the state mandates that all Medigap policies offered in the state must contain.[iv] Section 1882(p)(4)(B) of the Act specifically allows for inclusion of innovative benefits in one or more of the 10 standardized plans at the discretion of the state. Thus, the initiative for adding an innovative benefit originates from the issuer, but the state does not have to allow the addition.

The only criteria the statute provides for the state, or CMS, to use in determining whether an innovative benefit is acceptable is that the Medigap policy may include benefits "not otherwise available"; "cost-effective"; and must be "offered in a manner which is consistent with the goal of simplification" or standardization of Medigap policies. When it revised the NAIC Model Regulation to conform to the OBRA'90 requirements, the NAIC added a drafting note that states that an innovative benefit "should offer 'uniquely different' or 'significantly expanded' coverage." The drafting note further suggests that states should scrutinize requests for approval very carefully.[v] A handbook that the NAIC produced in

1991 to accompany the new 1991 NAIC Model Regulation stated, in a "Frequently Asked Questions" section, that –

> While [CMS] has stated it will not "second guess" such approvals on a case-by-case basis, it has said it will review approval patterns when considering continuing approval of a state's program.

2. *Vendor Discounts*

Section 1882(p)(7) states that the discount can only apply to the purchase of items or services not covered under the issuer's Medigap policies.[vi] We believe that this makes it clear that an issuer may offer vendor discount arrangements so long as they are treated as extra service features of a policy, not as benefits. If the arrangement merely provides policyholders a reduced price on an item or service and the policy does not actually pay any part of the cost of the item or service (like a deductible or coinsurance amount), then it would appear to be a vendor discount, rather than an innovative benefit (i.e., the policyholder pays for the item or service--even though at a reduced price--exclusively out of his or her own pocket). The issuer may have had to pay the vendor something to arrange the discount, but this amount is an administrative expense, most probably categorized as a marketing cost because the service is being presented as an extra "perk" that is made available to all purchases of the issuer's policies or to all purchasers of a particular policy that issuer offers. The purpose of the vendor discount is to make that issuer's product more attractive to potential buyers.

### C. State Flexibility Approving Innovative Benefits

The Act permits states flexibility to approve Medigap policies with different benefit structures under the "new or innovative benefits" provision. This flexibility authority is incorporated into the NAIC Model Regulation. This provision permits insurers to offer new or innovative benefits that are "in addition to" the benefits provided in a policy that meets the requirements of the NAIC Model Regulation – including the standardized groups of benefits.[vii] A drafting note accompanying the NAIC Model Regulation states that the new or innovative benefits provision "may be appropriate to add coverage or access to such benefits as prescription drugs, at-home recovery services and preventive medical care" and that any such benefit "should offer uniquely different or significantly expanded coverage." Model Regulation § 8C(11) (drafting note).

This section reviews CMS's position regarding:

1) Whether states may approve Medigap policies that include co-payments for the costs of hospital, physician and other services that are covered under Medicare Part A or Part B.
2) Whether the Act permits states to approve Medigap policies that include additional benefits such as vision, dental and generic prescription drug benefits, and what requirements apply to such benefits under the provision related to innovative benefits.
3) Whether Medigap insurers may make use of formularies, pharmacy networks generic substitution policies, or other techniques to manage prescription drug costs for plans including this coverage.
4) Whether disease management services, case management services, nurse advice lines and the like qualify as innovative benefits.

*1. Co-payments*

We have been asked whether the new or innovative benefits provision of the Act would permit states to approve policies that include a modest co-payment for the costs of hospital and physician services that are otherwise covered under Medicare Part A or Part B. The Act requires that all Medigap policies provide benefits that conform to the standard benefit packages set forth in the NAIC Model Regulation. As drafted, the NAIC Model Regulation requires that the benefits that must be covered include the entire amount of the deductible or coinsurance that applies with respect to a particular Medicare benefit. An

innovative benefit cannot effectively reduce any other benefits available in the standard package. While the introduction of co-payments might deter some of the excess utilization that the total first-dollar coverage provided by all Medigap policies for Part B services encourages, and might help to reduce Medigap premiums and Medicare program costs, under current law, such a benefit design would violate the standardization requirements. Thus, states would generally not be permitted to approve a Medigap policy that includes a co-payment applicable to hospital or physician services covered under Medicare Part A or Part B because the policy would not be covering the entire amount of the applicable benefit. If issuers are interested in steering policyholders to a preferred network of providers, we suggest they consider offering a Medicare SELECT policy. Medicare SELECT is discussed in more detail below.

*2. Additional Benefits*

The new or innovative benefits provision of the Act provides a basis for states to approve additional benefits to the 10 standard NAIC Medigap plans. These additional benefits, such as prescription drug coverage, vision benefits, dental benefits, may provide additional value to Medigap policyholders.

As the cost of prescription drugs continues to rise, we have been repeatedly asked about possible structures of prescription drug benefits that would qualify as an innovative benefit. For example, states are permitted to approve a prescription drug policy with a co-payment structure that encourages use of generic drugs as an innovative benefit. Thus, it would be permissible to add the following innovative benefit to a standard Medigap H, I, or J plan: Coverage for generic prescription drugs with an appropriate co-payment (such as $10), not subject to the deductible or coverage limit. Such a benefit would be *in addition to* the standard drug plan, which would only pay for drug benefits after the deductible is satisfied.

In approving such innovative benefits, states have considerable flexibility in approving lower deductibles, higher coverage maximums, and lower coinsurance amounts than the drug benefits offered under Plans H, I and J. For the same reason, the innovative benefits provision also provides flexibility in approving prescription drug programs with co-payments included.

*3. Alternative Prescription Drug Benefit Designs*

CMS has been asked whether it is permissible for insurers that offer Medigap plans H, I, and J to use a drug formulary to assure cost effective use of prescription drugs. Drug benefit designs that include pharmacy benefit managers, drug formularies and the like are appropriate to be offered in a Medicare SELECT context. We are unaware of any provision in the Act or the NAIC Model Regulation that precludes the use of a formulary or generic-substitution policy, or that requires brand drugs be covered (as opposed to generic drugs) as part of the standard benefit package. We conclude, therefore, that the Act does *not* prohibit Medicare SELECT insurers offering policies that cover prescription drugs from making use of formularies or other techniques to encourage cost-effective use of prescription drugs.

*4. Disease Management*

We consider disease management services, case management services, nurse advice lines and similar services to be innovative benefits. These services are not otherwise available to beneficiaries with a standard Medigap policy and are considered to be cost-effective.

**D. Guaranteed Renewability**

Some regulating authorities have construed the guaranteed renewability provision to preclude insurers from including new or innovative benefits in *existing* Medigap policies.[viii] Such a construction undermines the intent of the new and innovative benefits provision by not approving the introduction of such benefits. The Act includes a guaranteed renewability provision that bars insurers from nonrenewing Medigap policies based on health status or for reasons other than nonpayment of premium or material

misrepresentation. 42 U.S.C. § 1395ss(q)(1). Whether these innovative benefits are guaranteed renewable depends on how the Medigap issuer offers them, either (a) as an integral part of the policy or (b) as an optional rider to one of the standard plans. In either case, we conclude that states may approve the addition of new or innovative benefits to existing Medigap policies where the new benefits are included (or offered, in the case of riders) on a uniform basis for all similar policies at the time of renewal (even if these new benefits result in a modest premium increase).

If the issuer offers innovative benefits on a mandatory basis, which is to say it is an integral part of the policy, then these benefits are included with the standard benefits that are guaranteed renewable. If the issuer offers innovative benefits on a voluntary basis, which is to say added to the standard benefits through a rider to the policy, then these innovative benefits would not be guaranteed renewable (but the Plan's standard benefits would be). However, the issuer must offer the rider to all policyholders (with a particular Plan), or to none of them. This would ensure uniform treatment of all Medigap beneficiaries and would ensure that renewal is not impermissibly tied to the health status of any beneficiary.

### E. Medicare SELECT and Preferred Provider Networks

This section addresses whether an innovative benefit that contains network arrangements or certain other managed care features can be added to a regular Medigap policy or whether such a benefit design could only be approved as an addition to a Medicare SELECT policy. It also reviews recent proposed changes to the Office of Inspector General's (OIG's) Safe Harbors to the Anti-Kickback statute.

#### *1. Background*

Medicare SELECT is a special type of Medigap policy that may reduce costs for insurers and premiums for beneficiaries, while requiring beneficiaries to receive services from a preferred network of providers. Unlike conventional Medigap policies, which must by law cover cost-sharing amounts for most Medicare services provided by qualified providers or suppliers, a Medicare SELECT issuer may selectively contract with providers or suppliers to waive cost-sharing amounts it would otherwise have to pay on behalf of policyholders, subject to certain conditions to ensure access, coverage, and quality. In other words, Medicare SELECT is similar to a preferred provider network; enrollees may receive reduced supplemental benefits (e.g., less coverage of Medicare cost-sharing) if they use an out-of-network provider.

Historically, there were fewer obstacles to Medicare SELECT issuers contracting with hospital networks to provide inpatient hospital services, because under the OIG Safe Harbor regulation, hospitals could waive cost-sharing amounts under contracts with Medicare SELECT insurers, without either the issuer or the hospital running afoul of the Anti-Kickback statute. However, OIG's interpretation of the Anti-Kickback statute impeded the ability of Medicare SELECT issuers to contract with a preferred network of physicians on a discounted basis, because the safe harbor did not extend to Part B providers and suppliers. The OIG has recently proposed changes to its Anti-Kickback Safe Harbor regulations that, if made final, would remove this obstacle to contracting on a discounted basis with physicians and other Part B providers and suppliers. Consequently, issuers interested in providing standard Medigap benefits or innovative benefits through preferred networks of hospitals, physicians and other providers should find it easier to do so once the OIG's Safe Harbor regulation becomes final. Savings achieved from having a directed and preferred provider network may be passed on to beneficiaries, such as in the form of innovative benefits described herein.

Whether innovative benefits that involve the use of preferred provider networks as part of their benefit designs could only be offered under the Medicare SELECT authority was a strongly debated issue in 1991.[ix] The position CMS took at that time was that the concept of standardized packages (i.e., packages in which the benefits are the same from state to state and policy to policy) does not adapt itself to managed care approaches that vary benefits based on the insured's behavior. Medicare SELECT seemed to be the statutory authority under which benefits could be varied based on behavior. In 1991, we did not

rule out the possibility that we might take a different position in the future based on a changed understanding of the marketplace. We indicated that there might be statutory change.

Such changes did occur. Medicare SELECT was eventually made permanent and expanded to all states that want to allow such policies. Given this change, we believe that continuing to maintain the principle established in 1991 that preferred or limited provider networks may be provided only in the Medicare SELECT context causes no impediment to innovation in the market place. Any state can now allow the sale of Medicare SELECT policies provided it adopts standards at least as stringent as those contained in section 10 of the NAIC model. Any issuer wishing to introduce an innovative benefit with network restrictions could do so as an addition to a Medicare SELECT policy. For instance, an issuer could offer a nonstandard drug plan that used a formulary and a pharmacy benefit manager as an addition to a SELECT policy.

*2. Office of the Inspector General Proposed Changes to Kickback Safe Harbors*

On July 29, 1991, OIG published final regulations (56 FR 35952) that, among other provisions, included a safe harbor for the waiver or reduction of coinsurance or deductible amounts (cost-sharing amounts) for inpatient hospital services paid for under the prospective payment system provided certain standards were met. See 42 CFR 1001.952(k)(1). The Department concluded that waivers of cost-sharing amounts for inpatient hospital services that complied with these standards would not increase costs to the Medicare program, shift costs to other payers, or increase patient demand for inpatient hospital services.

On November 5, 1992, the OIG issued an interim final rule (57 FR 52723) modifying the safe harbor to accommodate the waiver or reduction of inpatient hospital cost-sharing amounts made in accordance with a contract between the hospital and a Medicare SELECT issuer. Under the 1992 modified safe harbor, Medicare SELECT issuers can enter into contracts with hospitals to waive or reduce inpatient hospital cost-sharing amounts for Medicare SELECT enrollees, provided the other requirements of the safe harbor are met. On January 25, 1996, the Department published final regulations (61 FR 2122) that included the amendments to the safe harbor made by the interim final rule. In 1996, the OIG specifically declined to protect waivers of cost-sharing amounts for other than hospital inpatient services.

However, the OIG is preparing a notice of proposed rulemaking that, if proposed and made final, would create safe harbor protection for waivers of cost-sharing amounts for other providers. The regulation would supplement the current safe harbor to include waivers of cost-sharing amounts for Part A or Part B services for Medicare SELECT policyholders in accordance with an agreement between the Medicare SELECT issuer and a provider or supplier, provided that the waivers are otherwise permitted under applicable Medicare program laws, regulations, and policies. This would make clear that hospitals and physicians would not be prohibited by the Anti-Kickback statute from contracting with Medicare SELECT insurers on a discounted basis, or from waiving all or part of the coinsurance, when implemented in accordance with the safe harbor conditions.

*3. CMS Policy*

If the OIG proposes and finalizes the safe harbor regulations noted above, CMS would permit most providers to waive part or all of the coinsurance under a Medicare SELECT contract without affecting their Medicare payments. The one exception to this policy is that discounts on cost-sharing amounts would generally not be allowed if CMS reimburses the provider using exclusively charge-based payments (*e.g.*, charge-based payments that are non-fee schedule, non-prospective or composite, non-capped payments). Consequently, CMS policy would not present an obstacle to hospitals, physicians, and all suppliers who CMS reimburses on a prospective payment system, capped fee payments or fee schedule (or the lesser of fee schedule or charges) to take advantage of the safe harbor.[x] We believe that the combination of the OIG safe harbor and CMS policy would make it easier for Medicare SELECT issuers to broaden their preferred provider networks. Any savings achieved by these provider discounts could be passed along to Medicare SELECT beneficiaries in the form of innovative benefits or reduced premiums.

## III. Summary

We believe that there is room for growth in innovative benefit design. In addition to the nonstandard prescription drug packages mentioned above (either above whatever cap applies to the plan in the case of plans H, I, and J or as an addition to any of the other plans A-G), the statute and regulations may be interpreted to permit development of innovative benefits such as: case management or disease management services; nurse advice lines; prescription drug; vision, dental, and hearing benefits that cover examinations; and basic models of prosthetic devices not covered by Medicare such as eyeglasses, dentures, or hearing aids rather than just providing discounts for these items; chronic care/ home health benefit; or various kinds of wellness promotion programs such as exercise classes, weight management, smoking cessation, stress management, or nutritional counseling services.

Issuers interested in providing standard Medigap benefits or innovative benefits through preferred provider networks of hospitals, physicians, and other providers or supplier would be permitted to do so by offering Medicare SELECT products. Discounts negotiated with network providers will be protected under the Anti-kickback statute once the OIG's Safe Harbor regulation is proposed and made final. Savings achieved from restricting the provider network could be passed on to beneficiaries in the form of innovative benefits described herein.

**Where to get more information:**

If you have any questions regarding this attachment, contact Gale Arden, Director of the Private Health Insurance Group, the Centers for Medicare and Medicaid Services, via e-mail at garden@cms.hhs.gov or via telephone at (410) 786-6810.

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[i] Three states (Wisconsin, Minnesota, and Massachusetts) had been experimenting with standardizing Medigap benefits prior to enactment of OBRA'90. These states were allowed to keep their alternative forms of standardized policies. All other states had to allow only the standardized packages to be sold. However, a state could restrict the number of policies sold in the state to fewer than 10, so long as they required issuers selling any of the other standardized policies to offer the most basic or core policy, Medigap plan A, to any prospective buyer.

[ii] Specifically, section 1882(p)(4)(A)(i) of the Act requires –

> Except as provided in subparagraph (B) . . . no State with a[n approved] regulatory program . . . may provide for or permit the grouping of benefits (or language or format with respect to such benefits) under a [Medigap] policy unless such grouping meets the applicable 1991 NAIC Model Regulation . . . .

Section 1882(p)(8) provided for the application of civil money penalties not to exceed $25,000 for each such violation of the standardization requirements by an issuer (or $15,000 per violation in the case of a seller who is not an issuer of a policy.

[iii] The NAIC survey conducted in 1999 indicates that some of the benefits that different states have approved include vision care, mental health, smoking cessation, weight management, a nonstandard prescription drug benefit, travel benefits (other than the foreign emergency travel benefit contained in plans C-J), and a high deductible plan arrangement (approved before BBA'97 added the high deductible versions of plans F and J).

[iv] Whether states could include their otherwise mandated benefits in the standard 10 Medigap policies was a hotly debated issue during the 9 months the NAIC was given to amend its model regulation pursuant to OBRA'90. CMS (then HCFA) determined that only 10 standard

plans could be allowed nationwide. Therefore, state-mandated benefits could not be applied to Medigap policies.

[v] A drafting note at the end of section 8 of the model regulation states:

> **Drafting Note**: Use of new or innovative benefits may be appropriate to add coverage or access to such benefits as prescription drugs, at-home recovery services and preventive medical care. Any such innovative benefit, however, should offer uniquely different or significantly expanded coverage.

Another drafting note at the same location reiterates the statutory language with respect to vendor discounts and provides some examples of what likes of discounted services could be provided under this separate authority:

> **Drafting Note**: The Omnibus Budget Reconciliation Act 1990, 42 U.S.C. § 1395ss(p)(7), does not prohibit the issuers of Medicare supplement policies, through an arrangement with a vendor for discounts from the vendor, from making available discounts from the vendor to the policyholder or certificateholder for the purchase of items or services not covered under its Medicare supplement policies (for example: discounts on hearing aids or eyeglasses).

[vi] During the 9 month period the NAIC had to amend the model pursuant to OBRA'90, the question was raised whether an issuer that offered one of the drug plans (plan H, I, or J) could also offer a discount mail-order pharmacy service as a vendor discount in conjunction with these drug policies or with any of its policies. A strict reading of the statute would appear to prohibit such an offer of the discounted service, however no conclusions were reached. This issue has added relevance today.

[vii] HHS regulations allow states to "approve the addition of new or innovative benefits to an otherwise approved standardized plan." 63 Fed. Reg. 67078, 67079 (Dec. 4, 1998) (preamble to notice recognizing NAIC model standards).

[viii] Under Massachusetts and New York law, policy changes unilaterally made by insurers are not permitted under the guaranteed renewability requirements. See Mass. Regs. Code tit. 211, § 71.03; N.Y. Comp. Codes R. & Regs. tit. 11, § 52.22(b)(1).

[ix] The fact that Medicare SELECT was newly authorized by OBRA'90 and was restricted to a time limited demonstration in only 15 states, added to the controversy.

[x] For example, CMS currently reimburses providers and suppliers on a "charges only" basis for new technology ("inherent reasonableness for new technologies"), DME in certain instances ("inflation based charges"), and blood/blood products.